510(k) Summary
per 21 CFR §807.92

NOV 13 2012

Sponsor: Boston Scientific Corporation
One Boston Scientific Place
Natick MA 01760

Contact Person: Rachel Owens

Phone Number: 763-494-1491

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Prepared: 12 October 2012

Trade Name: Encore™ 26 Advantage Kit

Common Name: Balloon Inflation Kit

Common name of the kit components:

Inflation device, insertion tool, Y-adaptor and torque device

Classification: II

Product Code: MAV
21 CFR 870.1650

Predicate Device: Encore ™ 26 Advantage Kit (K120694, 03 April 2012).

Device Description:

The Encore™ Advantage Kit is a kit of sterile disposable devices intended for use as accessories for percutaneous coronary angiography (PTCA) procedures. They allow for balloon inflation and wire control.

Intended Use

The Encore™ 26 Advantage Kits are intended for use as accessories for percutaneous coronary angiography (PTCA) procedures. They create and monitor balloon inflation and facilitate wire introduction and control.

Individual Device Intended Use:

- Encore™ 26 Inflation Device: Used with balloon dilation catheters to create and monitor pressure in the balloon, and to deflate the balloon.
- GateWay™ Plus Y-Adapter: Used for providing hemostasis around guidewires, balloon dilatation catheters, and other therapeutic devices
- Torque Device: Used for guidewire manipulation during general intravascular procedures.
- Guidewire Insertion Tool: Used for percutaneous introduction and placement of guidewires in vascular procedures.

Substantial Equivalence

The proposed Encore ™ 26 Advantage Kit design, materials, manufacturing process and intended use are substantially equivalent to the currently marketed Encore ™ 26 Advantage Kit (K120694).

Summary of Non-Clinical Testing

Design verification was performed to verify the performance and usability of the Torque Device remains substantially equivalent to the predicate device via K123024. No additional testing was required for kit inclusion. Sterility testing was performed to verify the overall substantial equivalence to the predicates. No additional biocompatibility testing was required.

Summary of Clinical Testing

Clinical Evaluation was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Boston Scientific Corporation
Ms. Rachel Owens
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

NOV 13 2012

Re: K123214
Trade Name: Encore™ 26 Advantage Kit
Regulation Number: 21 CFR 870.1650
Regulation Name: Syringe, balloon Inflation
Regulatory Class: Class II
Product Code: MAV
Dated: October 12, 2012
Received: October 15, 2012

Dear Ms. Owens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K123214

Device Name: Encore™ 26 Advantage Kit

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- Guidewire Insertion Tool: Used for percutaneous introduction and placement of guidewires in vascular procedures.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123214